METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

CITISINA (IN HOUSE)

PRODUCT CODE: 886	CAS Nº: 485-35-8	ANALYSIS Nº: 116/25	
MANUFACTURER BATCH:	CTS20241201	CERTIFICATE ID:	46.314
SUPPLIER BATCH:	----	MANUFACTURING DATE:	22/12/2024
METAPH BATCH:	0020525	EXPIRY DATE:	21/12/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	Almost white crystalline powder	Slightly yellowish crystalline powder
Odour	Characteristic	Characteristic (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Specific optical rotation	-118º / -125º	-121º
Melting point	154 - 157 ºC	154.4 ºC
Bulk tapped density	40-60 g/100 ml	Complies (*)
Particle size	80 mesh	Complies (*)
Loss on drying	=< 2.0 %	0.02 %
Residue on ignition	=< 0.1 %	0.04 %
Assay	=> 98.0 %	99.8 %
Heavy metals	=< 10 ppm	Complies (*)
Arsenic	=< 2 ppm	Complies (*)
Lead	=< 2 ppm	Complies (*)
Related substances		
N-Methylcytisine	=< 0.5 %	0.4 %
N-Formylcytisine	=< 0.5 %	Not Detected
Unspecified impurities	=< 0.3 %	< 0.01 %
Total impurities	=< 1.5 %	0.4 %
Residual solvents		
Methanol	=< 3000 ppm	< 50 ppm
Chloroform	=< 60 ppm	< 50 ppm
Acetone	=< 5000 ppm	687 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Salmonella	Absence/1g	Absence/1g
E. Coli	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
C. Albicans	Absence/1g	Absence/1g
P. Aeruginosa	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer Specifications

REMARKS

Botanical name: Leguminosae plant Sophora alopecuroides.
Part used: Seed.

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Analysis date: 19/05/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349
H. G. (WAICOME PHARMA)
No. 138 YuWu Road
XinMin Town
408302 Chonqing

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Cytisine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the containers tightly closed in a cool and dry place, and protected from the light.

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